The Interstate Shellfish Sanitation Conference deliberated the issues presented to Task Force III and took the following actions. Note: Bold and underline denotes text to be added; strikeout denotes text to be deleted.

**ISSUE NUMBER: 99-308** 

**SPECIFIC REFERENCE:** ISSC Procedures, proposed new Procedure X., page 14.

TEXT OF ISSUE:

**REQUESTED ACTION:** Modify the ISSC Procedures, page 14, by adding new Procedure X.:

PROCEDURE X. PROCEDURES FOR HANDLING SHELLFISH DEALER PETITIONS FOR REVIEW OF STATE DECISIONS TO REVOKE CERTIFICATION OR REFUSAL TO CERTIFY OR RE-CERTIFY SHELLFISH DEALERS FOR LISTING ON THE ICSSL.

SECTION 1. If a state lacks legal authority to provide for administrative review of its decision to revoke certification or in refusing to certify or re-certify a shellfish dealer for listing on the ICSSL, the following review process shall be available to the shellfish dealer upon petition to the ISSC:

Subdivision a. Only petitions from shellfish dealers regarding a state shellfish control agency's decisions with respect to the interstate certification process for listing on the ICSSL shall be covered by this procedure.

Subdivision b. Upon a state shellfish control agency's decision to revoke certification or to refuse to certify or re-certify a shellfish dealer for listing on the ICSSL, the shellfish dealer shall be entitled to petition the ISSC for administrative review, which shall take place prior to the shellfish dealers' removal from the ICSSL.

Subdivision c. Petitions for review shall be made in writing to the ISSC Board Chairman, with a copy to the state shellfish control agency as listed in the ICSSL as well as to the appropriate FDA Regional Office. The petition shall state the following:

<u>Subdivision 1. Identity of the shellfish dealer and state shellfish control</u> agency involved in the matter;

Subdivision 2. A statement requesting that the ISSC convene a Dealer Certification Review Committee to review the matter; and

Subdivision 3. What state shellfish control agency decision is being

challenged.

Subdivision d. Upon a state shellfish control agency's decision to revoke certification or to refusal to certify or re-certify a shellfish dealer for listing on the ICSSL, said agency shall give written notice within ten (10) days to the affected shellfish dealer who is entitled to petition the ISSC for administrative review of its decision.

Such notice shall include the basis and reasons relied upon by the state shellfish control agency in its decision and information upon which the shellfish dealer can petition the ISSC for administrative review.

SECTION 2. Upon receipt of a petition from a shellfish dealer, the ISSC Board Chairman shall do the following:

Subdivision a. Within thirty (30) days of receipt of the shellfish dealer's petition, the

ISSC Board Chairman shall convene a Dealer Certification Review Committee either to confirm or overrule the state shellfish control agency's decision.

<u>Subdivision b. The ISSC Board Chairman shall appoint the following members to</u> the Dealer Certification Review Committee:

Subdivision 1. Two industry members from states other than the affected shellfish dealer's state;

<u>Subdivision 2. Two state shellfish control agency members from states other</u> than the affected shellfish dealer's state;

Subdivision 3. One member from the US Food and Drug Administration and one member from the National Marine Fisheries Service; and

Subdivision 4. A state shellfish control agency member from a state other than the affected shellfish dealer's state who shall serve as the seventh member and Chairman of the Dealer Certification Review Committee. The Chairman shall vote only to break a tie among the other members. The Committee Chairman shall decide on the procedures to be followed during the hearing including the order of presentation of the parties' cases and time limitations. Any hearsay statement or document that is relevant and authenticated may be submitted by the parties.

<u>Subdivision c. The Dealer Certification Review Committee shall convene at a time and location convenient to all participants as determined by the Committee Chairman.</u>

Subdivision d. The parties may be represented by counsel.

Subdivision e. Fourteen (14) days prior to the date set for the hearing, the parties shall file with the ISSC Executive Director a brief and a notice listing all documents that party intends to introduce at the hearing. The parties shall serve the brief and notice upon each other including copies of the documents not already in each other's possession. The ISSC Executive Director shall provide copies of the briefs and notices upon the other Dealer Certification Review Committee members in advance of the hearing. The state shellfish control agency's brief shall contain the following:

Subdivision 1. A brief statement justifying its position to revoke certification or refusal to certify the shellfish dealer for listing on the ICSSL; and

Subdivision 2. All facts and laws upon which its bases its decision.

The shellfish dealer's brief shall contain the following:

 $\underline{\text{Subdivision 3. A brief statement indicating why it should be certified and}} \\ \text{listed on the ICSSL; and}$ 

Subdivision 4. All facts and laws upon which it bases its position.

Subdivision f. Upon conclusion of the presentations, the Dealer Certification Review Committee shall confer and reach a decision within 24 hours. The decision shall be reduced to writing and shall include the reasons, facts, and laws that support the decision.

Subdivision g. If the Dealer Certification Review Committee's decision supports the interstate certification and ICSSL listing of the shellfish dealer, the state shellfish control agency shall submit FDA Form 3039 with three (3) business days so that the shellfish dealer can be listed on the ICSSL.

Renumber subsequent Procedures.

**RATIONALE:** Procedure IX provides remedy for state or non-state parties regarding program non-conformities. The ISSC has interpreted that Procedure IX does not provide remedy for industry members who feel they are being unfairly regulated by a state shellfish control agency. The newly proposed Procedure X. provides remedy for the industry.

**COST INFORMATION:** N/A.

**ACTION BY 1999 TASK FORCE III:** Recommended No Action on Issue 99-308. Rationale: Historically, the purpose and scope of the administrative procedures of the ISSC Constitution, By-Laws and Procedures have been limited to addressing the relationship between the USFDA and State shellfish control authorities. Task Force III appreciates the importance of administrative remedy for the industry but is reluctant to suggest the ISSC as the forum. Task Force III recommended appointment of a committee by the ISSC Executive Board Chairman to study the appropriateness of ISSC involvement in administrative remedies for the shellfish industry.

ACTION BY 1999 GENERAL ASSEMBLY: Adopted recommendation of 1999 Task Force III.

### **ACTION BY 2000 ADMINISTRATIVE PROCEDURES COMMITTEE:**

RECOMMENDATIONS: Recommended referral of Issue 99-308 back to Task Force III with a recommendation that a survey be conducted to determine how many states do not have administrative review procedures for the listing and de-listing of shellfish dealers on the ICSSL.

ACTION BY 2000 TASK FORCE III: Recommended adoption of the recommendations of the 2000 Administrative Procedures Committee as amended: Recommended referral of Issue 99-308 back to Task Force III with a recommendation that a survey be conducted to the Administrative Procedures Committee with a request that the Committee, with the assistance of the ISSC Executive Office, conduct a survey to determine how many States do not have administrative review procedures for the listing and de-listing of shellfish dealers on the ICSSL.

ACTION BY 2000 GENERAL ASSEMBLY: Adopted recommendation of 2000 Task Force III.

**ACTION BY 2001 ADMINISTRATIVE PROCEDURES COMMITTEE:** The committee request this issue be referred back to the Administrative Procedures Committee for action pending the results of a survey which will be conducted immediately following this meeting.

**ACTION BY 2001 TASK FORCE III:** Recommended no action on the language included in Issue 99-308 but supports the completion of the State Survey which should provide useful information.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force III.

**ACTION BY USFDA:** Concurred with Conference action.

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**ISSUE NUMBER: 00-302** 

**SPECIFIC REFERENCE:** ISSC Constitution Article IV., SECTION 4, page 2.

TEXT OF ISSUE:

**REQUESTED ACTION:** Modify ISSC Constitution Article IV., SECTION 4, page 2:

<u>SECTION 4.</u> The Treaty Tribes of Western Washington, signatory to the Consent Decree regarding shellfish sanitation with the State of Washington, shall have a <del>non-</del> voting member on the Executive Board designated by the tribal parties to the Consent Decree, whose name shall be submitted by the Northwest Indian Fisheries Commission.

**RATIONALE:** The Executive Board discussed this issue at the March 2000, Executive Board meeting and voted to submit an issue with a recommendation to extend voting privileges to the tribal representative.

COST INFORMATION (IF AVAILABLE): None.

**ACTION BY 2000 TASK FORCE III:** Recommended referral of Issue 00-302 to appropriate committee with instructions to develop criteria to determine the basis for selection of tribal representation on the Executive Board. Additionally, the Committee is requested to examine the impact of establishing additional representation on the composition and function of the Executive Board. The Task Force expressed appreciation for the participation and contributions of the current Northwest Treaty Tribes representative.

ACTION BY 2000 GENERAL ASSEMBLY: Adopted recommendation of 2000 Task Force III.

**ACTION BY 2001 EXECUTIVE COMMITTEE:** Recommended No Action. Rationale: It would be inappropriate for any entity with involvement confined to part of a single state to have voting privileges equal to that of an entire ISSC region.

**ACTION BY 2001 TASK FORCE III:** Recommended adoption of Executive Committee's recommendations on Issue 00-302.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force III.

**ACTION BY USFDA:** Concurred with Conference action.

\*\*\*

**ISSUE NUMBER: 00-303** 

**SPECIFIC REFERENCE:** ISSC Constitution Article IV., page 2.

TEXT OF ISSUE:

**REQUESTED ACTION:** Modify ISSC Constitution Article IV., page 2 by adding new SECTION 5.:

SECTION 5. The Board Chairman, with the approval of the Board, shall appoint a voting Consumer Advisory representative.

Renumber subsequent sections.

**RATIONALE:** Consumer advisory organizations continue to have more involvement in food safety issues. In recent years, their role in affecting food safety policy has continued to increase. The ISSC Constitution does not provide for consumer input into the organization's deliberative process. The addition of a Consumer Advisory representative to the Executive Board would provide for consumer representation. The Executive Board discussed this issue at the March, 2000, Executive Board meeting and voted to submit an issue recommending appointment of a Consumer Advisory representative with voting privileges.

COST INFORMATION (IF AVAILABLE): Travel expenses to attend meetings.

**ACTION BY 2000 TASK FORCE III:** Recommended adoption of Issues 00-303 as amended:

Modify ISSC Constitution Article IV., page 2 by adding new SECTION 5.:

SECTION 5. The Board Chairman, with the approval of the Board, shall appoint a <u>non-</u>voting Consumer Advisory representative. **The Consumer Advisor shall serve a two-(2) year term.** 

Renumber subsequent sections.

The Task Force also recommended that the initial Consumer Advisory term shall be one (1) year to coincide with the biennial meeting schedule and further recommended appointment of an appropriate committee as determined by the Conference Chairman with instructions to examine the impact of establishing additional representation on the composition and function of the Executive Board.

ACTION BY 2000 GENERAL ASSEMBLY: Adopted recommendation of 2000 Task Force III.

**ACTION BY 2001 EXECUTIVE COMMITTEE:** The Executive Committee was requested to examine the impact of granting voting privileges to a Consumer Advisor. The Executive Committee recommended No Action. Rationale: The Executive Committee feels that the consumer advisor to the board should eventually have a vote on the board since the larger consumer groups represent national interest. The Executive Committee will continue to investigate which group will be appropriate and make recommendations to the board at a later date.

**ACTION BY 2001 TASK FORCE III:** Recommended adoption of the Executive Committee's recommendations on Issue 00-303.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force III.

ACTION BY USFDA: Concurred with Conference action.

\*\*\*

**ISSUE NUMBER: 00-304** 

**SPECIFIC REFERENCE:** ISSC Constitution Article IV., page 2.

**TEXT OF ISSUE:** 

**REQUESTED ACTION:** Modify ISSC Constitution Article IV., page 2, by adding new SECTION 5.: [Ed. note: Voting delegate actions on Issue 00-303 may result in modification of numbering of this section,]

SECTION 5. The National Restaurant Association (NRA), American Liver Foundation (ALF), American Gastroenterological Association (AGA), and Food Marketing Institute (FMI) shall each have a non-voting member on the Executive Board.

Renumber subsequent Sections.

**RATIONALE:** Adding the Associations listed above to the Board as non-voting members will help with the education effort for those susceptible individuals eating raw shellfish. Their participation will give the ISSC a better opportunity to understand the best possible way to reach those individuals that are in the atrisk groups.

**COST INFORMATION:** Travel expenses to attend meetings.

**ACTION BY 2000 TASK FORCE III:** Recommended referral of Issue 00-304 to appropriate committee as determined by the Conference Chairman to examine the impact of establishing additional representation on the composition and function of the Executive Board. The Task Force further recommended that the voting delegates request the Executive Board to extend an invitation to these organizations and the American Medical Association to encourage immediate participation in the activities of the Interstate Shellfish Sanitation Conference.

ACTION BY 2000 GENERAL ASSEMBLY: Adopted recommendation of 2000 Task Force III.

**ACTION BY 2001 EXECUTIVE COMMITTEE:** Recommended No Action. Rationale: The Executive Board Chairman presently has the discretion to appoint Board Advisors as appropriate.

**ACTION BY 2001 TASK FORCE III:** Recommended adoption of the Executive Committee's recommendation on Issue 00-304.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force III.

**ACTION BY USFDA:** Concurred with Conference action.

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# **ISSUE NUMBER: 01-301**

**SPECIFIC REFERENCE:** Definitions.

**TEXT OF ISSUE:** 

### **REQUESTED ACTION:**

Modify definition of Authority as: (7) Authority-Federal, state or local shellfish control authority including domestic and foreign within the current MOU AND including foreign states where there is no MOU for the importation of raw molluscan shellfish which are responsible for enforcement of this Model Ordinance and any other similar codes, laws and regulations.

# Modify definition of Importer as:

(49) **Importer** means any dealer who introduces molluscan shellfish into domestic commerce. An importer has ownership of the shellfish, but need not take physical custody of the shellfish.-To have all the requirements as related to the FDA SEAFOOD HACCP Regulation as described in CFR 123.3(g) and its addendums and successors be applied to the importer

### **Create new definition for Cooked:**

Cooked-To have all portions of the shellstock (whether domestic or foreign) to reach the internal temperature with sufficient time as to meet or exceed the definition of cooked as identified in the current FDA Food Code and its addendums or successors AND to have verification of this process through HACCP documentation.

**RATIONALE:** These definitions will provide for the importation of "cooked" product from foreign sources to insure that pathogens have reduced to an acceptable level and to have the foreign Authority (whether federal state or local level in a foreign nation) insure that the product that is labeled as "cooked" has met the thermal processing requirements. Product has entered into domestic commerce labeled as cooked and was found to be the source of a food borne illness which in fact failed to be thermally processed.

COST INFORMATION (IF AVAILABLE): None.

**ACTION BY 2001 TASK FORCE III:** Recommended referral of Issue 01-301 to the Executive Board for immediate action. The Executive Board is requested to involve the appropriate agencies in addressing this issue and develop interim guidance concerning the definitions of cooked and uncooked shellfish. The Executive Board is further requested to include some type of timeline or deadline for completion of task by working group.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force III.

**ACTION BY USFDA:** Concurred with Conference action.

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**ISSUE NUMBER: 01-302** 

**SPECIFIC REFERENCE:** ISSC Policy Setting Documents.

**TEXT OF ISSUE:** 

**REQUESTED ACTION:** Add text after the third paragraph in the policy statement ending with "... should seek the advice of their physician."

Modify National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish (1997 Version), Chapter 6, and "ISSC Policy Statement – Consumption of Raw Molluscan Shellfish":

<u>Policy Statement</u> Molluscan shellfish.

To reduce the potential.....

Certain medically compromised individuals... seek the advice of their physician. <u>In an effort to further reduce illnesses and deaths that are associated with naturally occurring marine bacteria such as *Vibrio vulnificus* and *Vibrio parahaemolyticus*, the ISSC recognizes that there are commercially available raw molluscan shellfish products that have been processed to reduce the risk from certain naturally occurring marine pathogens such as the *Vibrio* sp. Persons that desire to consume raw molluscan shellfish but are concerned about their risk are advised to consult their supplier and seek such products.</u>

**RATIONALE:** Recognizing that products processed to reduce naturally occurring marine pathogens have the potential to lower the rate of associated illnesses will help the acceptance of those (lower *Vibrio-*risk) products.

# COST INFORMATION (IF AVAILABLE) None.

**ACTION BY 2001 TASK FORCE III:** Recommended referral of Issue 01-302 to the Executive Board for review. The Executive Board is requested to review, within sixty (60) days of the close of the conference, the current ISSC Policy Statement for Consumption of Raw Molluscan Shellfish and include language addressing Post Harvest Treatments.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force III.

**ACTION BY USFDA:** Concurred with Conference action.

# **ISSUE NUMBER: 01-303**

**SPECIFIC REFERENCE:** Change all references to post-harvest treatment processing in Model Ordinance and NSSP.

TEXT OF ISSUE: Change the use of terminology "post harvest treatment" and "post harvest processing" to "pathogen reduction process(ing)."

RATIONALE: None.

**COST INFORMATION (IF AVAILABLE): None** 

**ACTION BY 2001 TASK FORCE III:** Recommended No Action. Rationale: The term "Post Harvest Treatment is recognized. There may be reasons other than pathogen reduction for post harvest treatment.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force III.

**ACTION BY USFDA:** Concurred with Conference action.

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# **ISSUE NUMBER: 01-304**

**SPECIFIC REFERENCE:** Add <u>PROCEDURE XI. PROCEDURE FOR HANDLING ISSUES</u> and change the current PROCEDURE XI to XII and so on...

#### TEXT OF ISSUE:

# **REQUESTED ACTION: Add New Procedure XI:**

# XI. PROCEEDURE FOR HANDLING ISSUES.

SECTION 1. A "Call for Issues" shall be mailed to each member 120 days prior to a biennial or interim meeting.

SECTION 2. Issues shall be submitted to the Executive office 60 days prior to a biennial or interim meeting.

SECTION 3. For the purpose of issue procedures there shall be three kinds of issues; growing area, plant sanitation, and administrative.

SECTION 4. There shall be four prescribed criteria for issues:

Subdivision a. Each Issue shall be submitted uniformly using a standard ISSC Issue Submission Form.

Subdivision b. Each growing area or plant sanitation issue shall include specific Model Ordinance reference by section and paragraph, and specific language for suggested revisions.

<u>Subdivision c.</u> Each growing area or plant sanitation issue shall include appropriate documentation and public health significance such as literature references or data.

Subdivision d. Each growing area or plant sanitation issue shall include a cost-benefit analysis to be used as an aid to determine the regulatory impact of new requirements while providing economic efficiency.

SECTION 5. The Board Chairman, with approval of the Board, shall appoint a 9-member Issue Review Committee. Membership shall consist of the ISSC Chairman, three members from regulatory, three members from industry, one representative from FDA, and one member from NMFS. The duties of the Committee will be as outlined in Procedures XI of the ISSC CONSTITUTION, BY-LAWS and PROCEDURES.

<u>SECTION 6.</u> The objective of the Issue Review Committee shall be to review all proposed issues with respect to criteria for content, format ,and for adherence to the requirements outlined in Procedures XI of the ISSC CONSTITUTION, BY-LAWS and PROCEDURES.

SECTION 7. The Issue Review Committee, in reviewing the submitted issues, shall:

<u>Subdivision a. Recommended NO ACTION on previously submitted issues that do not contain</u> new information and issues lacking adequate supporting information.

<u>Subdivision b. Recommended NO ACTION on growing area and plant sanitation issues that do not contain appropriate documentation of both the problem and public health significance such as literature reference or data.</u>

Subdivision c. Recommended NO ACTION on growing area and plant sanitation issues that do not include a cost-benefit analysis that shall be used as an aid to determine the regulatory impact of new requirements while providing economic efficiency.

SECTION 8. The Issue Review Committee shall recommend to the Executive Board assignment of each new issue for the appropriate Task Force. The Committee may provide in writing its reason for the action it has taken.

SECTION 9. The Issue Review Committee may make recommendations which may include:

Subdivision a. Making recommendations to the Executive Board linking similar issues to the appropriate Task Force. The Committee must provide in writing its reason for the action it has taken.

Subdivision b. Making editorial changes (grammatical, spelling, or format only); and Subdivision c. Making substantive changes (must discuss with submitter).

 $\overline{\text{XI-}\text{XII.}}$  PROCEDURE FOR HANDLING RESOLUTIONS.

Renumber subsequent Procedures.

RATIONALE: None.

**COST INFORMATION (IF AVAILABLE):** None.

**ACTION BY 2001 TASK FORCE III:** Recommended referral of Issue 01-304 to the Executive Board for development of a concise procedure for the handling of issues. The Task Force recommended the procedure be used for the next conference and submitted as an issue.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force III.

**ACTION BY USFDA:** Concurred with Conference action.

\*\*\*

**ISSUE NUMBER: 01-305** 

**SPECIFIC REFERENCE:** Constitution of the ISSC Article IV, Section 9.

**TEXT OF ISSUE:** 

**REQUESTED ACTION:** Modify Constitution, Article IV, and Section to read:

Section 9. The Executive Committee... Industry representation on the Executive Committee shall be appointed by the Chairman of the Executive Board, <u>at each biennial meeting</u>, with recommendation from the industry members of the Board.

RATIONALE: None.

**COST INFORMATION (IF AVAILABLE):** None.

ACTION BY 2001 TASK FORCE III: Recommended adoption of 01-305 as submitted.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force III.

**ACTION BY USFDA:** Concurred with Conference action.

\*\*\*

**ISSUE NUMBER: 01-306** 

**SPECIFIC REFERENCE:** Constitution Article IV, Section 9.

**TEXT OF ISSUE:** 

**REQUESTED ACTION**: Modify Constitution Article IV, Section 9.

<u>Subdivision 1.</u> The Executive Committee at a minimum shall consist of the Board Chairman, Vice Chairman, Office Manager, Program Chairman, one Industry Executive Board member, and the immediate past Board Chairman. The function of the Executive Committee is to provide administrative guidance to the Executive Office of the ISSC for management of daily activities. <del>Industry representation on the Executive Committee shall be appointed by the Chairman of the Executive Board with recommendation from the industry members of the Board.</del>

Subdivision 2: Industry representation on the Executive Committee shall be appointed by the Chairman of the Executive Board with recommendation from the industry members of the Board. Industry representation on the Executive Committee shall be as follows: one (1) industry member representing Regions 1, 2 and 3; one (1) industry member representing Regions 4 and 5; and one (1) industry member representing Region 6.

**RATIONALE:** Since the ISSC was formed in 1982, the shellfish industry has been a participant as voting members of the Board and non-voting members of the General Assembly. The industry has a vested interest in the affairs and day-to-day operation of the ISSC. Because of the diversity of industry nationwide, there needs to be greater industry representation on the Executive Committee as it provides administrative guidance to the Executive Office of the ISSC for management of daily activities.

COST INFORMATION (IF AVAILABLE): None.

**ACTION BY 2001 TASK FORCE III:** Recommended No Action. Rationale: The issue is adequately addressed by action on 01-305.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force III.

**ACTION BY USFDA:** Concurred with Conference action.

# **ISSUE NUMBER: 01-307**

**SPECIFIC REFERENCE:** Constitution of the ISSC Article IV, Section 7.

**TEXT OF ISSUE:** 

**REQUESTED ACTION:** Modify Constitution, Article IV, Section 7:

Section 7. Elected Board members shall serve four, (4), two (2), year terms. Terms of the elected...

RATIONALE: None.

COST INFORMATION (IF AVAILABLE): None.

ACTION BY 2001 TASK FORCE III: Recommended adoption of Issue 01-307 as submitted.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force III.

**ACTION BY USFDA:** Concurred with Conference action.

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## **ISSUE NUMBER: 01-308**

**SPECIFIC REFERENCE:** Constitution Article IV Section 8.

**TEXT OF ISSUE:** 

**REQUESTED ACTION**: Modify Constitution Article IV Section 8.

Section 8. The Board shall elect a Chairman and Vice Chairman. Board officers shall be elected every four years for a two, (2), year term at the Executive Board meeting following the voting general assembly of the regular biennial Conference meeting. An industry member may be elected Chairman or Vice Chairman of the Board. When presiding over the voting general assembly, an industry person serving as the Chairman or Vice Chairman may vote to break a tie as allowed under Robert's Rules of Order. New Officers shall take office.

**RATIONALE:** The ISSC has been in existence since 1982. The shellfish industry has been a participant since the ISSC's inception as voting members of the Board and non-voting members of the General Assembly. Traditionally, the Board Chairman and Vice Chairman have been elected from the State-voting delegates. There is no reason why an industry representative cannot be Chairman of the Board. The Chairman does not vote except in case of a tie at the Board meeting or General Assembly. Board members under the ISSC Constitution are full voting members of the Board. The authority and duties of the Board Chairman and Vice Chairman are closely prescribed in the Constitution and By-laws. The election of an industry chairman would not give industry a vote in the General Assembly except in the rare instance of a tie.

### **COST INFORMATION (IF AVAILABLE):** None.

ACTION BY 2001 TASK FORCE III: Recommended adoption of Issue 01-308 as amended.

Section 8. The Board shall elect a Chairman and Vice Chairman for a two (2), year term at the Executive Board meeting following the voting general assembly of the regular biennial Conference meeting. An industry member may be elected Chairman or Vice Chairman of the Board. When presiding over the voting general assembly, an industry person serving as the Chairman or Vice Chairman may vote to break a tie as allowed under Robert's Rules of Order. New Officers shall take office.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force III.

**ACTION BY USFDA:** Concurred with Conference action.

\*\*\*

**ISSUE NUMBER: 01-309** 

SPECIFIC REFERENCE: Constitution of the ISSC Article IV, Section 8.

TEXT OF ISSUE:

**REQUESTED ACTION:** Modify Constitution, Article IV, Section 8:

Section 8. The Board shall elect a Chairman and Vice Chairman <u>for a two, (2), year term Board Officials</u> shall be elected every four (4) at the Executive Board meeting following the voting general assembly of the regular biennial Conference meeting. New officers...

RATIONALE: None.

COST INFORMATION (IF AVAILABLE): None.

**ACTION BY 2001 TASK FORCE III:** Recommended No Action. Rationale: Issue 01-309 is adequately addressed by action on 01-308.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force III.

**ACTION BY USFDA:** Concurred with Conference action.

\*\*\*

ISSUE NUMBER: 01-310

**SPECIFIC REFERENCE:** Constitution Article IV, Section 9.

TEXT OF ISSUE:

**REQUESTED ACTION:** Modify Constitution Article IV, Section 9 to read:

<u>Subdivision 1.</u> The Executive Committee at a minimum shall consist of the Board Chairman, Vice Chairman, Office Manager, Program Chairman, one industry Executive Board member, and the immediate past Board Chairman. The function of the Executive Committee is to provide administrative guidance to the Executive Office of the ISSC for management of daily activities. <del>Industry representation on the Executive Committee shall be appointed by the Chairman of the Executive Board with recommendation from the industry members of the Board.</del>

Subdivision 2: Industry representation on the Executive Committee shall be appointed by the Chairman of the Executive Board with recommendations from the industry members of the Board. When the Executive Committee is functioning as the selection committee for the Executive Director, the Executive Committee shall have minimum industry representation as follows:

One (1) industry member representing Regions 1, 2 and 3; one (1) industry member representing Regions 4 and 5; and one (1) industry member representing Region 6.

<u>Subdivision 3:</u> The Executive Committee shall also function as the selection committee in the event that there is need to hire an Executive Director.

<u>Subdivision 4</u>: In selecting candidates to recommend to the Executive Board for employment as the Executive Director, the Executive Committee at a minimum shall:

- 1. Create a written job description that makes it clear that the Director serves at the pleasure of the Board, and provides a written description of duties.
- 2. <u>Advertise the position widely in a number of different forums (newspapers, website, Business Daily, fisheries journals, etc.).</u>
- 3. Identify a contact person (not the current Executive Director) for candidates who have questions.
- 4. Identify a number of qualified candidates through written resumes.
- 5. <u>Scrutinize the candidates, and screen their qualifications against the duties of the Executive Director.</u>
- 6. Select the applicants best suited for the job, and interview.
- 7. Make a recommendation of top three candidates to the Board.

**RATIONALE:** Eventually there will be a need to replace the Executive Director of the ISSC. A process should be in place for this event before the need arises.

**COST INFORMATION (IF AVAILABLE):** Cost estimates will vary depending venues selected for publication of ads soliciting resumes, when and how the Executive Committee will meet to interview candidates, whether the Board elects to pay the travel costs of candidates for interview, and whether the Board elects to pay office relocation costs or New Director relocation costs. Cost estimate for the advertising, and interview process are estimated at <\$ 5,000.

**ACTION BY 2001 TASK FORCE III:** Recommended referral of Issue 01-310 to the Executive Board to develop a policy for the hiring of an Executive Director. The Task Force recommended the Executive Board use the language contained in Issue 01-310 as a guide.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force III.

**ACTION BY USFDA:** Concurred with Conference action.

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## **ISSUE NUMBER: 01-311**

**SPECIFIC REFERENCE:** Constitution Article IV, new Article VIII.

**TEXT OF ISSUE:** 

### REOUESTED ACTION:

Article IV. Executive Board, Officers, Committees.

Sections 1–6 [text unchanged]

Section 7. The Board shall elect a Chairman, and Vice Chairman, and Treasurer. Board officers shall...

<u>Section 8.</u> The Executive Committee at a minimum shall consist of the Board Chairman, Vice Chairman, <u>Treasurer</u>, Office Manager, Program Chairman, one industry Executive Board member, and the immediate past Board Chairman.

Section 9 - 11. [text unchanged]

Article VIII. Duties of the Treasurer.

Section 1. The Treasurer shall serve as the financial review officer of the Conference and shall, in conjunction with the Executive Committee, oversee the administration and disbursement of funds by the Executive Director.

Section 2. The Board Treasure shall arrange for an annual audit of the financial affairs of the organization, including the financial statement prepared by the Executive Director. At a minimum, the Treasurer shall:

- A. Prepare a solicitation for bids, evaluate bids and select an auditor to perform a full audit of the Executive Director's annual financial report, and the fiscal affair of the Conference. The auditing firm shall specialize in non-profit organizations receiving grants from NOAA, FDA and EPA, and be familiar with A-133 audits and other similar federal audit.
- B. Recommended the selected auditor to the Board for contract..
- C. Meet with the auditor as necessary during the course of the audit, and to receive the final report.
- D. Forward the report to the Board with appropriate recommendations.

Section 3: The Executive Director shall make available to the auditor all records of the Executive Board, Executive Committee, and the Executive Office, including receipts, copies of all contracts, agreements, memoranda and notes that relate to the fiscal administration of Conference business, procurement of bids, letting of contracts, and expenditures of conference or contractual funds.

Section 4: The Treasurer may at his discretion anytime during the Conference's fiscal year, review the financial records of the Conference.

Articles VIII Article XII Article IX - XIII [Renumber Articles as appropriate].

**RATIONALE:** The level of funding administered by the ISSC is growing rapidly. The preparation of the financial report and the selection and employment of an auditor are currently done by the Executive Director. In most organizations, there is a Treasurer who is the officer entrusted with the custody of its funds, and disbursement of funds. Since the ISSC custody and disbursement of funds is handled directly by the Executive Director, a need exists for a periodic reviews of the organization's expenditure's by a specified officer who also arranges for the audit of the Conference's fiscal affairs. A limited Treasurer function needs to be restored in the ISSC, and because all non-profits should be subject to annual review by auditing firms that specialize in non-profit audits, a need exists to have a specialized auditing firm perform this function. To accomplish its public health objectives, the ISSC must be fiscally sound and above reproach.

**COST INFORMATION (IF AVAILABLE):** Estimated cost is \$7,500 - \$10,000 depending on the time that must be expended for the first audit. Funding for this expense can be allocated across grants as an eligible administrative item. Cost will drop for following audits.

**ACTION BY 2001 TASK FORCE III:** Recommended No Action. Rationale: Issue 01-311 is adequately addressed by action on 01-312.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force III.

**ACTION BY USFDA:** Concurred with Conference action.

## **ISSUE NUMBER: 01-312**

SPECIFIC REFERENCE: Constitution Article V.

**TEXT OF ISSUE:** Constitution Article V.

Sections 1-8 [text unchanged]

<u>Section 9</u>: The Board shall direct the Executive Director to collect membership fees. .... The registration fee amount shall be set by the Board.

Section 10. The Board shall cause an audit to be made of the Executive Director's financial report annually. The Board shall direct the Executive Director to prepare annually a written financial report listing receipts, expenditures, and financial balance of the ISSC for the previous financial year...

Section 11: The Board shall appoint an Audit Committee annually.

Subdivision 1: No member of the Executive Committee shall be a member of the Audit Committee.

Subdivision 2: The responsibilities of the Committee shall be:

- (1) <u>Prepare a solicitation for bids, evaluate bids and select an auditing firm to perform a full audit of the Executive Director's annual financial report and the fiscal affairs of the Conference.</u>
- (2) Recommend the selected auditor to the Board for contract. The audit firm shall specialize in non-profit organizations receiving grants from NOAA, FDA and EPA, and be familiar with A-133 audits and other similar federal audits
- (3) Meet with the auditor as necessary during the course of the audit, and to receive the final report.
- (4) Forward the report to the Board with appropriate recommendations.

<u>Subdivision 3: The Executive Director shall make available to the auditor to all records of the Executive Board, Executive Committee, and the Executive Office, including ISSUE 01-312</u>

receipts, copies of all contracts, agreements, memoranda and notes that relate to the fiscal administration of Conference business, procurement of bids, letting of contracts, and expenditures of conference or contractual funds.

Section 10: Section 12. The Board shall authorize... [Renumber other sections as appropriate]

**RATIONALE:** The level of funding administered by the ISSC is growing rapidly. The disbursement of funds, preparation of the financial report and the selection and employment of an auditor are currently done by the Executive Director, a function performed by the Treasurer in most organizations. Because the Treasurer function does not exist in the ISSC, and because all non-profits should be subject to annual review by auditing firms that specialize in non-profit audits, a need exists to have a Committee perform this function. Since the Executive Committee is charged with advising the Executive Director concerning the daily affairs of the ISSC and working with the Executive Director to manage the financial affairs of the ISSC, the Executive Committee is excluded from participation on the Audit Committee. To accomplish its public health objectives, the ISSC must be fiscally sound and above reproach.

**COST INFORMATION (IF AVAILABLE):** Estimated cost is \$7,500 - \$10,000 depending on the time that must be expended for the first audit. Funding for this expense can be allocated across grants as an eligible administrative item. Cost will drop for following audits.

**ACTION BY 2001 TASK FORCE III:** Recommended referral of Issue 01-312 to the appropriate committee as determined by the Conference Chairman.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force III.

**ACTION BY USFDA:** Concurred with Conference action.

\*\*\*

# **ISSUE NUMBER: 01-313**

**SPECIFIC REFERENCE:** Constitution Article IV and V.

#### **TEXT OF ISSUE:**

## Modify Constitution Article IV. Executive Board, Officers, Committees:

Sections 1 - 11 [text unchanged]

Section 12. The Board will appoint a Performance Review Committee which shall meet annually to evaluate the performance of the Executive Director and the Executive Office as provided in Article V, Section 3 and Article XII.

### Modify Constitution Article V. Duties of the Board

Sections 1 and 2. [text unchanged]

<u>Section 3.</u> The Board may retain the services of an Executive Director who shall serve as chief administrator of the Conference. <u>The Board shall provide for an annual review of the performance of the Executive Director and Executive Office.</u>

## Add to Constitution new Article IX. Executive Office Annual Performance Review:

Section 1. To ensure that the goals, objectives and interests of the ISSC are being met by the Executive Office, the Executive Director and performance of the Executive Office shall be subject to an annual review conducted by the Performance Review Committee.

Section 2. The Performance Review Committee shall be appointed annually by the Executive Board. This committee shall be comprised of no more than five persons and shall include at least one shellfish producing state member, one industry member and one non-producing state member. No member of the Executive Committee shall be a member of this committee.

Section 3. The Performance Review Committee shall have the cooperation of the Executive Board, the Executive Committee, the Executive Director, and the Executive Office, and shall have access to all records of the Executive Board, Executive Committee, and the Executive Office, including administrative, fiscal and personnel affairs, receipts, copies of all contracts, agreements, memoranda and notes that relate to the administration of Conference business, procurement of bids, letting of contracts expenditures of conference or contractual funds, and the performance of the Executive Director's duties enumerated in the ISSC Constitution and By-laws.

Section 4. The performance review shall include, but is not limited to, the timeliness and completeness of the performance of the functions of the Executive Office with respect to meeting the needs of the Conference and the Director's mandated duties. Because the Constitution in Article 8 lists management of the Executive Office and supervision of Executive Office staff as an Executive Director duty, staff failures should also reflect on the Executive Director's performance.

Section 5. The Performance Review Committee may interview the Executive Director, Executive Committee, Executive Office staff, contractors, auditors and any other parties for information pertinent to the performance review.

Section 6. The Committee shall forward a written report summarizing its findings concerning the performance of the Executive Director and the Executive Office and the Committee's recommendations to the Executive Board.

Section 7. After its review of the report, the Executive Board shall post notice of the availability of the report on the ISSC web site. The full report shall be made available to any member of the ISSC upon request.

Renumber Articles IX –XII as Articles X – XIII.

**RATIONALE:** Accomplishment of the ISSC's public health goals and objectives is dependent of the performance of its Executive Director and Executive Office. Because of the wide disparity and geographical spread of the ISSC membership, members have no factual information for evaluating performance and accomplishment. Since the Executive Committee is charged with advising the Executive Director concerning the daily affairs of the ISSC and working with the Executive Director to manage the financial affairs of the ISSC, the Executive Committee is excluded from participation on the committee to assure an objective review.

**COST INFORMATION (IF AVAILABLE):** Estimated cost is \$500 - \$2,000 depending on the travel expenses of the committee.

**ACTION BY 2001 TASK FORCE III:** Recommended referral of Issue 01-313 to the Executive Board with the recommendation that the Executive Committee develop policy and criteria for the performance review of the Executive Director.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force III.

**ACTION BY USFDA:** Concurred with Conference action.

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### **ISSUE NUMBER: 01-314**

**SPECIFIC REFERENCE:** By-Laws and Procedures Reference: Article IV, Section 10.

# **TEXT OF ISSUE:**

Action: Delete Travel Committee as a Standing Committee in Article IV, Section 10 of the Constitution, By-Laws and Procedures. Section 10 would read as follows:

SECTION 10. The following committees shall be designated as standing committees and shall

convene as needed or as directed by the Executive Board or Chairman of the Conference: Education, Foreign Relations, Issue Review, Patrol, Research

Guidance, Resolutions, Shellfish Restoration. , Travel. ...

**RATIONALE:** Executive Committee has the responsibility of making decisions regarding travel.

COST INFORMATION (IF AVAILABLE): None.

ACTION BY 2001 TASK FORCE III: Recommended adoption of Issue 01-314 as submitted.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force III.

**ACTION BY USFDA:** Concurred with Conference action.

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# **ISSUE NUMBER: 01-315**

**SPECIFIC REFERENCE:** Procedure II. Section 2 and 2; Procedure XII, Sections 1-7.

**TEXT OF ISSUE:** 

## PROCEDURE II. PROGRAM.

SECTION 1. To achieve its goal, the ISSC will adopt a NSSP <u>Guide for the Control of Molluscan Shellfish Model Ordinance and companion Handbook</u> for sanitary control of shellfish that is adequate to ensure that the shellfish produced in a state that complies with these guidelines will be safe and sanitary. This NSSP <u>Guide for the Control of Molluscan Shellfish Model Ordinance and companion Handbook</u> shall be called the National Shellfish Sanitation Program (NSSP).

SECTION 2. The ISSC shall adopt a NSSP <u>Guide for the Control of Molluscan Shellfish</u> <u>Model Ordinance and companion Handbook</u> as the NSSP, effective January 1998. <del>Until the effective date of the NSSP Model Ordinance, the 1995 National Shellfish Sanitation Program Manual of Operations, Part I and II, and amendments, shall be adopted as the NSSP.</del>

# PROCEDURE XII. PROCEDURE FOR HANDLING AND DISSEMINATING INTERPRETATIONS OF THE MANUAL BY FDA.

<u>SECTION 1.</u> A request for Interpretation must be submitted to FDA Headquarters (<u>Office of Field Programs</u> Shellfish Program Implementation Branch) through either an FDA Regional Office or the ISSC Executive Director according to the following routes:

<u>Subdivision a.</u> The interpretation request is submitted to the <u>Office of Field Programs</u> Shellfish Program Implementation Branch (SPIB) following the administrative chain of communication from industry to the State, to the FDA Regional Office, to FDA Headquarters; or

Subdivision b. The interpretation request is submitted to the ISSC Executive Director by industry, a State, or the general public. The ISSC forwards the interpretation request to the Office of Field Programs SPIB for a response.

<u>SECTION 2.</u> The interpretation request submitted to the Office of Field Programs-SPIB must be written and include the following:

Subdivision a. ...

Subdivision b. ...

Subdivision c. ...

Subdivision d. ...

<u>SECTION 3.</u> Within seven (7) days, the Office of Field Programs SPIB will acknowledge receipt of the letter to the requestor and FDA's Division of Federal and State Relations (DFSR) and report which branch in FDA is responsible for developing the interpretation.

<u>SECTION 4.</u> All requests for interpretations must be sent to <u>the Office of Field Programs</u>. <u>The Office of Field Programs</u> <u>SPIB</u> will decide if the request is a technical or policy issue. <u>The Office of Field Programs</u> <u>SPIB</u> will develop technical interpretations and the <u>FDA Office of Seafood</u> <u>Shellfish Sanitation Branch (SSB)</u> will develop policy interpretations. Therefore, in the following subdivisions, if the request is a policy issue substitute <u>FDA Office of Seafood</u> <u>SSB</u> for <u>the Office of Field Programs</u> <u>SPIB</u>.

Subdivision a. Within sixty (60) days of acknowledgment of the letter, the Office of Field Programs SPIB will provide a draft proposal to the FDA Regional Offices, FDA Office of Seafood SSB, the ISSC Executive Director, and DFSR for comment. The ISSC Executive Director shall distribute the draft proposal to the requestor and ISSC members from states, industry, and the general public.

Subdivision b. ...

<u>SECTION 5.</u> Comments on the Draft Interpretation.

<u>Subdivision a.</u> The FDA Office of Seafood <u>SSB</u>, the Regional Offices, ISSC Executive Director, and DFSA have thirty (30) days from receipt to comment on the draft proposal to <u>the Office of Field Programs</u> <u>SPIB</u>. The ISSC Executive Director is responsible from receiving, consolidating, and forwarding to <u>the Office of Field Programs</u> <u>SPIB</u> comments from ISSC members from states, industry, and the general public.

<u>Subdivision b.</u> The FDA Office of Seafood <u>SSB</u>, the FDA Regional Offices, ISSC Executive Director, and DFSR may request, in writing to <u>the Office of Field Programs SPIB</u>, an additional thirty (30) days to comment on the draft proposal.

SECTION 6. Action on Draft Interpretation Comments.

Subdivision a...

Subdivision 1. ... Subdivision 2. ...

Subdivision b. ...

<u>SECTION 7.</u> The Office of Field Programs SPIB shall disseminate final interpretations to the ISSC and DFSR for dissemination as follows:

Subdivision a. ...

<u>Subdivision b.</u> Upon receipt of the final interpretation, DFSR shall distribute it to the FDA Regional Offices and the Office of Field Programs SSB.

**RATIONALE:** Procedures should reflect the correct names of organizations within the FDA.

COST INFORMATION (IF AVAILABLE): None.

ACTION BY 2001 TASK FORCE III: Recommended adoption of Issue 01-315 as submitted.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force III.

**ACTION BY USFDA:** Concurred with Conference action.

# ISSUE NUMBER: 01-121

**SPECIFIC REFERENCE:** 1999 Model Ordinance Chapter II @. 03.

TEXT OF ISSUE:

REQUESTED ACTION: ADD SECTION C DEALING WITH IMPORTATION OF "COOKED" PRODUCT

# B. Cooked Products

The Authority shall provide to the importer of record that all shellstock offered for importation has been harvested in Growing waters as defined in the current Model Ordinance.

**RATIONALE:** The importation of "cooked" product has relieved the importer of record of the obligation to verify through the Authority that the shellstock has not been harvested or exposed to Growing waters that contain toxic chemicals in excess of established known tolerance levels and therefore by passing the NSSP requirements as they apply to growing water certification. Shellstock has been imported that was labeled as "cooked" from questionable sources that failed to have any established tolerances for chemical/toxin contamination.

**COST INFORMATION (IF AVAILABLE):** Not available

**Note:** Issue 01-121 was referred from Task Force I to Task Force III.

**ACTION BY 2001 TASK FORCE III:** Recommended referral of Issue 01-121 to the Executive Board for immediate action. The Executive Board is requested to involve the appropriate Federal Agencies in addressing this issue.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force III.

**ACTION BY USFDA:** Concurred with Conference action.

\*\*\*

# **ISSUE NUMBER: 01-122**

**SPECIFIC REFERENCE:** 1999 Model Ordinance Chapter IV @.04.

TEXT OF ISSUE:

# REQUESTED ACTION: ADD SECTION F DEALING WITH IMPORTATION OF "COOKED" PRODUCT

## F. IMPORTATION OF "COOKED" PRODUCT

The Authority shall provide to the importer of record that all shellstock offered for importation has been harvested in Growing waters as defined in the current Model Ordinance.

**RATIONALE:** The importation of "cooked" product has relieved the importer of record of the obligation to verify through the Authority that the shellstock has not been harvested or exposed to Growing waters where marine biotoxins are reasonably likely to occur AND to have NO records as identified in E. (1)-(4) therefore by passing the NSSP Requirements as they relate to growing water classification. Shellstock has been imported labeled as "cooked" from questionable sources that failed to have any documentation of a contingency plan to be activated in the event of the presence of marine biotoxins AND further to have no biotoxins control measures that could be identified.

COST INFORMATION (if available): Not available.

Note: Issue 01-122 was referred from Task Force I to Task Force III.

**ACTION BY 2001 TASK FORCE III:** Recommended referral of Issue 01-122 to the Executive Board for immediate action. The Executive Board is requested to involve the appropriate Federal Agencies in addressing this issue.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force III.

**ACTION BY USFDA:** Concurred with Conference action.

\*\*\*

**ISSUE NUMBER: 01-123** 

SPECIFIC REFERENCE: 1999 Model Ordinance Chapter II @.02 D(2).

**TEXT OF ISSUE:** 

**REQUESTED ACTION:** Add an additional Established Tolerance Level Chapter II A.02 D (2) (d) (vi).

The authority shall consider any shellstock labeled as cooked or pasteurized to have been thermally processed to destroy pathogens.

**RATIONALE:** The application of a thermal process to destroy pathogens can be added to the Risk Management strategy to provide the Authority with an established tolerance level as defined in Section B under definitions.

**COST INFORMATION:** None.

**Note:** Issue 01-123 was referred from Task Force I to Task Force III.

**ACTION BY 2001 TASK FORCE III:** Recommended referral of Issue 01-123 to the Executive Board for immediate action. The Executive Board is requested to involve the appropriate Federal Agencies in addressing this issue.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force III.

ACTION BY USFDA: Concurred with Conference action.

\*\*\*

ISSUE NUMBER: 01-210

**SPECIFIC REFERENCE:** Model Ordinance Reference: Chapter X .03.

TEXT OF ISSUE:

**REQUESTED ACTION:** Modify X.03 Other Model Ordinance Requirements to read:

Each dealer and importer shall comply with requirements specified in Chapter XI.03, Chapter XII.03, Chapter XII.03, and Chapter XIV.03 AND any other chapters and sections of this Model Ordinance that may apply that are appropriate to the plant and the food being processed. However, monitoring and records

<u>IF</u> required for these conditions and practices <u>shall be made available to the FDA and to the appropriate State shellfish standardization inspector and State shellfish standardization officer upon request within a reasonable time as to determine the status of shellstock to be processed, unless specifically stated.</u>

**RATIONALE**: The Authority will have access to all records to determine compliance with the Model Ordinance in a reasonable time if the shellstock is acceptable.

COST INFORMATION (IF AVAILABLE): Not Available at this time.

**Note:** Issue 01-210 was referred from Task Force II to Task Force III.

**ACTION BY 2001 TASK FORCE III:** Recommended referral of Issue 01-210 to the Executive Board for immediate action. The Executive Board is requested to involve the appropriate Federal Agencies in addressing this issue.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force III.

**ACTION BY USFDA:** Concurred with Conference action.

\*\*\*

### **ISSUE NUMBER: 01-223**

SPECIFIC REFERENCE: Model Ordinance Reference: Definition

### **TEXT OF ISSUE:**

- (92) Shellfish means all species of:
  - (a) Oysters, clams or mussels, whether:
    - (i) Shucked or in the shell;
    - (ii) Fresh, or frozen; and
    - (iii) Whole or in part; and
    - (iv) <u>Heat processed, except for low acid canned foods; and</u>
      Scallops in any form, except when the final product from is the adductor muscle only.

RATIONALE: Literature and studies of food borne outbreaks involving molluscan shellfish indicate that the only etiology is the contamination of the growing waters. This identifies the source of the shellstock as the only true critical control point in any hazard analysis. Within the United States all shellfish, even that product that is going to low acid canned food trade, is harvested in compliance with the National Shellfish Sanitation Program (NSSP). Recent food borne outbreak(s) in New York, due to Norwalk like virus in clams, have brought to light that certain imported molluscan shellfish products fail to comply with the requirements of the NSSP. These products were labeled as "cooked" and therefore not required to meet the standards for raw shellfish set forth in the Model Ordinance. Investigation found that the implicated product was indeed raw and came from a country that is not a member of the ISSC. In order to meet the objective of the NSSP "to provide a mechanism for health officials and consumers to receive information as to whether lots of shellfish shipped in interstate commerce meet acceptable and agreed upon sanitation and quality criteria", all molluscan shellfish products that are not heat processed equivalent to the low acid canned foods must come from countries that agree to meet the standards of the NSSP. Changing the definition of "shellfish" will place cooked products under the NSSP and eliminate the shipment of misbranded, adulterated products.

# COST INFORMATION (IF AVAILABLE): Not available.

**Note:** Issue 01-223 was referred from Task Force II to Task Force III.

**ACTION BY 2001 TASK FORCE III:** Recommended referral of Issue 01-223 to the Executive Board for immediate action. The Executive Board is requested to involve the appropriate Federal Agencies in addressing this issue.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force III.

**ACTION BY USFDA:** Concurred with Conference action.

### 2001 RESOLUTIONS

SUBMITTER: Alfred Sunseri RESOLUTION #01-001

DATE SUBMITTED: July 23, 2001

### **ACTION REQUESTED:**

[ ] Task Force III
[ X ] General Assembly
[ ] Executive Board

**SUBJECT:** Industry Member May Chair ISSC

### **TEXT OF RESOLUTION:**

Whereas, the Interstate Shellfish Sanitation Conference, (ISSC), has been in existence since September 21, 1982; and

Whereas, any person who is interested in promoting the availability of safe, wholesome shellfish may become a member of the ISSC; and

Whereas, the shellfish industry has been participants of the ISSC since the Conference's formation; and Whereas, the duties of the ISSC Chairman and Vice Chairman include, presiding at all meetings of the Board and during Conference meetings; and

Whereas, the duties of the ISSC Chairman and Vice Chairman are clearly articulated and limited by the ISSC Constitution and By-Laws; and

Whereas, under Robert's Rules of Order, the presiding officers of an organization have the authority to do only the things that are assigned to the office by the bylaws; and

Whereas, the key duties of the Chairman and Vice Chairman of the ISSC are to keep order, be fair and impartial, and protect the rights of all of the members; therefore

Be It Resolved, that the ISSC Executive Board strongly consider electing an Executive Board member representing the shellfish industry as Chairman or Vice Chairman of the ISSC.

**ACTION BY 2001 RESOLUTION COMMITTEE**: Refer Resolution 01-001 for consideration by Task Force III.

ACTION BY 2001 TASK FORCE III: Recommended adoption of Resolution 01-001 as amended.

## **TEXT OF RESOLUTION:**

Whereas, the Interstate Shellfish Sanitation Conference, (ISSC), has been in existence since September 21, 1982; and

Whereas, any person who is interested in promoting the availability of safe, wholesome shellfish may become a member of the ISSC; and

Whereas, the shellfish industry has been participants of the ISSC since the Conference's formation; and Whereas, the duties of the ISSC Chairman and Vice Chairman include, presiding at all meetings of the Board and during Conference meetings; and

Whereas, the duties of the ISSC Chairman and Vice Chairman are clearly articulated and limited by the ISSC Constitution and By-Laws; and

Whereas, under Robert's Rules of Order, the presiding officers of an organization have the authority to do only the things that are assigned to the office by the bylaws; and

Whereas, the key duties of the Chairman and Vice Chairman of the ISSC are to keep order, be fair and impartial, and protect the rights of all of the members; therefore

Be It Resolved, that the ISSC Executive Board strongly consider electing an Executive Board member representing the shellfish industry as Chairman or Vice Chairman of the ISSC.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force III.

**ACTION BY USFDA:** Concurred with Conference action.

\*\*\*

SUBMITTER: PAC-RIM Shellfish Sanitation Conference RESOLUTION #01-002

**DATE SUBMITTED: July 23, 2001** 

## **ACTION REQUESTED:**

[X] Task Force III
General Assembly
Executive Board

**SUBJECT:** Uncertified Imported Shellfish

## **TEXT OF RESOLUTION:**

*Whereas*, the increase in importation of uncertified shellfish has caused concern for State public health regulators, the molluscan shellfish industry and the general public: and

*Whereas,* shellfish from uncertified and non-MOU sources do not have federal Food and Drug Administration (FDA) oversight to assure compliance of shellfish standards required by the NSSP, and

Whereas, the federal Food and Drug Administration (FDA) has responsibility for monitoring and enforcing national laws governing imported food products: and

*Whereas*, the FDA does not have adequate resources to adequately detect uncertified imported shellfish that may enter the country through normal channels of trade or those that may be misbranded as "cooked" or labeled as other types of seafood, and

*Whereas*, the FDA does not currently have mechanisms to reliably identify uncertified imported shellfish that may enter the country through normal channels of trade or those that may be misbranded as "cooked" or labeled as other types of seafood, and

*Whereas*, the FDA does not routinely review HACCP Plans for raw and cooked shellfish during Seafood HACCP inspections of importers,

Be It Further Resolved, that the ISSC encourage the FDA and State shellfish control authorities to develop a method to coordinate the identification and removal of uncertified imported shellfish. This coordination effort may include, a) the notification by the FDA to the State control authority when uncertified imported shellfish is identified, b) outreach activities to the shellfish industry, and/or c) the development of a database to identify sources of uncertified imported shellfish and the firms importing uncertified imported shellfish. Be it further resolved, that the FDA explore its regulatory policies regarding uncertified imported shellfish to include potential regulatory actions based of federal misbranding laws and Seafood HACCP regulations.

ACTION BY 2001 RESOLUTION COMMITTEE: Recommended adoption as submitted.

ACTION BY 2001 TASK FORCE III: Recommended adoption as submitted

**ACTION BY 2001 GENERAL ASSEMBLY:** Adopted recommendation of 2001 Task Force III. **ACTION BY USFDA:** Concurred with Conference action.

\*\*\*

SUBMITTER: Lori Gerzina and Francis Okino RESOLUTION #01-003

DATE SUBMITTED: July 23, 2001

# **ACTION REQUESTED:**

[ ] Task Force III[ ] General Assembly[ X ] Executive Board

**SUBJECT:** Association of Food and Drug Officials (AFDO) actions to encourage conference participation by non-producing states

### TEXT OF RESOLUTION:

*Whereas*, the purpose of the National Shellfish Sanitation Program is to promote and improve the sanitation of shellfish moving in interstate commerce and to protect the public health through federal/state cooperation and uniformity of state shellfish programs; and

Whereas, the regulatory Authority of each non-producing state has the legal authority to protect the public health from shellfish-borne illness through the regulation of processing and shipping in that state in accordance with the National Shellfish Sanitation Program Model Ordinance; and

*Whereas*, the Interstate Shellfish Sanitation Conference is the vehicle by which sound, uniform methods are developed and adopted into the National Shellfish Sanitation Program Model Ordinance; and

*Whereas*, the Interstate Shellfish Sanitation Conference is directed by and under the control of the various states, federal agencies and shellfish industry who join together to form the Conference; and

*Whereas*, delegates from non-producing states are entitled to participate in deliberations and vote on proposed amendments to the National Shellfish Sanitation Program Model Ordinance in the General Assembly; and

Whereas, the participation of non-producing states has declined in recent years; therefore,

**Be It Resolved,** that the ISSC Executive Board request that the AFDO president and AFDO Seafood Committee encourage non-producing states to participate in the ISSC; and

Be It Resolved, that the ISSC Executive Board request that AFDO increase support for the participation of non-producing states in ISSC activities; and

Be It Further Resolved, that the ISSC Executive Board increases participation of the ISSC in AFDO activities.

**ACTION BY 2001 RESOLUTION COMMITTEE**: Recommended Referral of Resolution 00-003 to the Executive Board.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Resolutions Committee.

**ACTION BY USFDA:** Concurred with Conference action.

SUBMITTER: ISSC Executive Committee

NUMBER: 01-004

DATE SUBMITTED: July 26, 2001

ACTION REQUESTED:

[X] General Assembly
[] Executive Board

RECOMMENDATIONS OF RESOLUTION COMMITTEE:

[X] Recommend Referral to General Assembly for Consideration
[] Recommend Referral to Executive Board for Consideration
[] Recommend Referral to Executive Board for Task Force Assignment or other appropriate action

**SUBJECT:** Resolution of Appreciation

### TEXT OF RESOLUTION:

**WHEREAS**, the biennial meeting of the Interstate Shellfish Sanitation Conference convened July 21-27, 2001, at the Norfolk Waterside Marriott in Norfolk, Virginia and

**WHEREAS**, several individuals and organizations were instrumental in contributing to the outstanding success of this meeting,

**THEREFORE, BE IT RESOLVED,** that the Interstate Shellfish Sanitation Conference goes on record expressing appreciation to:

## The Staff of the Norfolk Waterside Marriott: particularly,

Tania Martinez, Convention Services Coordinator Michael West, Convention Services Manager

## The volunteer ISSC staff:

Program Chairman, Robert Wittman, Virginia Department of Health Office Manager, William Eisele, New Jersey Department of Environmental Protection Nancy Ridley, Massachusetts Department of Public Health

## **Volunteer Task Force recorders:**

Nancy Ridley, Massachusetts Department of Public Health, Task Force II Debbie Rouse, Delaware Division of Water Resources

### **Industry sponsors and contributors to Chairman's Reception:**

Bevan's Oyster Company, Kinsdale, VA
Casey's Seafood, Newport News, VA
Cherrystone Aqua Farms, Cheriton, VA
Floyd Marketing Ltd., New Zealand
Gulf Oyster Industry Council, New Orleans, LA
Ipswich Maritime Products, Ipswich, MA
Little River Seafood, Reedville, VA
Old Biloxi Shrimp and Oyster Co., Biloxi, MS
P&J Oyster Co., New Orleans, LA
Rappahannock Seafood, Kilmarnock, VA
Sam Rust Seafood, Hampton, VA
Virginia Division of Shellfish Sanitation, Norfolk, VA

**AND BE IT FINALLY RESOLVED**, that the Conference direct the Executive Director to write a letter of appreciation to each of the above mentioned individuals and organizations.

**ACTION BY 2001 RESOLUTIONS COMMITTEE:** Recommended adoption of Resolution 01-004 as submitted.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Resolutions Committee.

**ACTION BY USFDA:** Concurred with Conference action.